

## REMARKS

### In the Claims:

Claims 45, 46, 48-50, 53, 58, and 60-62 are currently pending in this application. The Examiner rejected claims 45, 46, 48-50, 53, 58, and 60-62 under 35 USC § 102(b) as anticipated by U.S. Patent No. 5,800,526 ("Anderson"). Applicants have given additional consideration to Anderson and respectfully disagree with the Examiner that Anderson anticipates the claimed invention. In particular, Anderson does not teach or disclose a stent with 1) an integrally formed barb (*i.e.*, the barb has not been attached to the wire during the manufacturing process); 2) that points in a predetermined direction at an angle relative to a longitudinal axis of the stent; and 3) that is unbent with respect to the wire and is free of weakening due to bending.

Anderson describes only two ways to form a barb on a wire. First, the "barbs can be formed independently of the stent and subsequently attached to it by welding, brazing or another process with the equivalent effect." See Anderson; col. 6, lines 64-67. This is clearly a non-integral barb and such structures do not anticipate the claimed invention.

Anderson also describes barbs formed from a flat sheet of material, or a tube, "by chemically etching, laser cutting, or electronic discharge machining (EDM), and the like." See, *e.g.*, Anderson; col. 6, lines 60-63; col. 8, lines 52-54. Such barbs are oriented in alignment with the longitudinal axis of the stent and not at an angle relative to a longitudinal axis of the stent, as recited in the rejected claims. See, *e.g.*, Anderson; Figs. 1-7, 15, and 17. See also, Anderson; col. 4, lines 13; col. 7, lines 47-50 ("each of the barbs preferably faces in alignment with the common longitudinal axis when the multi-anchor stent is in an unexpanded configuration.") Thus, these unexpanded structures do not anticipate the claimed invention.

Furthermore, Anderson's expanded structures do not anticipate the claimed invention. In particular, although Anderson teaches that the barbs may be re-oriented when the stent is expanded, expansion of the Anderson stent results in 1) a barb that is

bent with respect to the wire and weakened due to bending; and/or 2) a barb that points in an undetermined, rather than a predetermined direction.

The Examiner asserts that Anderson's barbs are not bent during expansion of the stent. See Final Office Action dated July 16, 2007; p. 2. This contention, however, is refuted by the specification. First, Anderson teaches a pressure-expandable stent that necessarily experiences bending, distortion, and plastic deformation over the entire contour of the stent, including the connection between the barb and strut. Second, Anderson expressly teaches that expansion of the Anderson stent results in barbs that are oriented by bending or distorting the barbs. In particular, the specification teaches forming the stent using a step etching process "to remove portions of material so that the barbs will bend outwardly when the stent is expanded. In other words, . . . upon radial expansion of the stent, areas having less material will have a tendency to bend or distort." Emphasis added. See Anderson; col. 9, lines 19-25.

Even assuming, for the sake of argument, that Anderson teaches a stent with unbent integral barbs, Anderson does not teach a barb that points in a predetermined direction as recited in the claimed invention. As explained in Applicants' specification, "it is preferable to orient the barbs 314 properly so that they will point in the desired direction in relation to the longitudinal axis of the final stent shape." ¶205. The proper orientation is important to "ensure[] that the barbs 'catch' and engage the adjacent tissue." ¶206. Thus, predetermined orientation of the barb in the expanded configuration is an important aspect of the claimed invention.

In contrast, Anderson disparages stents where "exact placement of an anchoring stent . . . [is] critical for properly securing the stent," and provides a stent with "a plurality of barbs throughout the entire circumference of the stent . . . so that exact placement of the anchors is less critical." See e.g. Anderson; col. 3, lines 5-8; col. 3, lines 33-39. Because Anderson's stent is pressure expandable, the stent may be expanded "to any number of larger diameters." See Anderson; col. 7, lines 41-44. (Emphasis added). Moreover, "[t]he special expansion characteristics of the stent of the invention [allows] any portion of the stent that extends distally or proximally of the graft to continue to expand even when the graft has achieved its maximum cross-sectional dimension . . . ."

See Anderson; col. 8, lines 25-31. Because the expanded configuration of an Anderson stent is variable, and because the orientation of Anderson's barbs in the expanded configuration is effected by the manner and extent of expansion, the expanded orientation of Anderson's barb is not predetermined.

Finally, figures 16 and 17 of Anderson do not anticipate the claimed invention because neither discloses 1) integrally formed barbs; 2) that point in a predetermined direction at an angle relative to a longitudinal axis of the stent; and 3) that are unbent with respect to the wire and free of weakening due to bending. Furthermore, column 12, lines 52-65 of Anderson, which provides the sole description of the structures depicted in figures 16 and 17, does not teach or disclose a stent having all of these features.

With regards to figure 16, the specification says only that barbs can be "formed in the surface of the cylindrical elements . . . to provide a sandpaper effect of raised, pointed, directional bumps of the surface of the stent." See Anderson; col. 12, lines 52-60. With regards to figure 17, the specification states that "multiple barbs 142 also can be formed on the outer edges of the peaks and valleys of the cylindrical rings so that the barbs will be directed outwardly when the stent is expanded." See Anderson; col. 12, lines 60-65. As explained above, Anderson describes **only** two ways to form a barb: 1) welding, brazing, and the like; and 2) chemically etching, laser cutting, or electronic discharge machining. The first method results in non-integral barbs, and the second method results in barbs that are bent and weakened and/or barbs that do not point in a predetermined direction at an angle relative to a longitudinal axis of the stent.


In order to anticipate under § 102, an asserted reference must teach or disclose each and every element of the claimed invention. MPEP § 2131. Because Anderson does not teach or disclose each and every structural feature of independent claims 45 and 58, it does not anticipate the claimed invention. Claims 46, 48-50, and 53 depend directly or indirectly from claim 45, and claims 60-62 depend directly or indirectly from claim 58. Accordingly, Anderson does not anticipate any of these claims.

Applicants respectfully request that the rejection of claims 45, 46, 48-50, 53, 58, and 60-62 be withdrawn and that these claims be allowed to pass to issuance.

#### **SUMMARY**

Applicants believe that the present claims are distinguishable over the prior art cited in the Office Action dated July 16, 2007. Accordingly, Applicants believe that the present claims are patentable and that the application is in a condition for allowance. Applicants respectfully request that the Examiner withdraw the final rejection and either grant allowance of the application or issue a non-final Office Action based on new grounds. The Examiner is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,



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